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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,592	03/19/2004	William Galbraith	80154	9558
26253 7590 03/25/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER YU, MELANIE J				
ART UNIT		PAPER NUMBER		
1641				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/804,592

**Applicant(s)**

GALBRAITH, WILLIAM

**Examiner**

MELANIE YU

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 5, 6, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 January 2009 has been entered.

### ***Status of the Claims***

2. Claims 1, 5, 6, 54 and 55 are pending and are examined. Claims 2-4 and 7-53 have been canceled.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 54 and 55 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide sufficient support for the limitation of the "epoxy-activated insoluble support is not cross-linked" or the support being agarose. It is noted that applicant points to the

specification at example 1 for support for non cross-linked support which teaches sepharose 6B. However, the originally filed specification does not specifically teach that the sepharose 6B is non cross-linked and does teach non cross-linked epoxy activated supports. Furthermore, the specification does not specifically teach an agarose support and therefore does not provide sufficient support agarose supports. Additionally, any claim containing a negative limitation must have basis in the original disclosure. See MPEP § 2173.05(i). In this case the original disclosure only recites a support of Sepharose 6B and does not specifically teach non cross-linked epoxy activated supports.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahnen et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580) in view of Spring et al. (US 5,643,721) further in view of Degen et al. (US 5,567,615).

Grahnen et al. teach an apparatus comprising an insoluble support (sepharose column) having a ligand consisting of bromosulphophthalein attached thereto, which is capable of being bindable to albumin, without being exposed to albumin (pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*). Grahnen et al. fail to teach the ligand attached to the support via an epoxy linkage.

Spring et al. teach ligands attached to an agarose substrate by an epoxy linker may be an agarose substrate (col. 5, lines 50-55), in order to provide a mixture that dries in a film form on the surface to which it is applied.

Degen et al. teach a ligand having a hydroxyl group (col. 12, line 46) attached to a polymer support via an epoxy linker (col. 12, lines 41-47) and therefore teach attachment of a ligand that is epoxy-activated (epoxy linker activates the support, col. 13, lines 44-46), in order to provide attachment of ligands to a polymer substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus of Grahnen et al., an epoxy linkage between the ligand and the agarose support as taught by Spring et al., in order to provide a simple method of attaching ligands having a hydroxyl group to a substrate by way of a spontaneous covalent attachment as taught by Degen et al. Degen et al.

do not specifically teach a bromosulphophthalein ligand being attached to an agarose support. However, Degen et al. teach that epoxy linker attachment is advantageous for ligands having a hydroxyl group and Spring et al. teach that an epoxy linker is advantageous to link ligands to an agarose support. Since bromosulphophthalein comprises a hydroxyl group, Degen et al. teach the epoxy linkage would be a simpler and advantageous method of attachment of bromosulphophthalein to a substrate, and Spring et al. teach that it would have been obvious for the substrate that the epoxy linker attaches to, to be an agarose support. Therefore an epoxy linker is advantageously used to attach the ligand to the agarose substrate of Grahnen et al.

With respect to claims 5 and 6 and 25-27, Grahnen et al. teach that the insoluble support is contained in and supported in a column (affinity column with bromosulphophthalein as a ligand, pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*; and pg. 575, right column, last 2 paragraphs).

5. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahnen et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580) in view of Spring et al. (US 5,643,721) further in view of Degen et al. (US 5,567,615), as applied to claim 1, and further in view of Travis et al. (US 4,093,612).

Grahnen et al. in view of Spring et al. further in view of Degen et al. teach an epoxy-activated insoluble support having a bromosulphophthalein ligand attached thereto

without being exposed to albumin, wherein the support is cross-linked sepharose (pg. 574), but do not teach the support being non cross-linked.

Travis et al. teach a support for removing albumin (col. 2, lines 13-19) wherein the support is agarose in the form of either packed sepharose (grades 2B, 4B or 6B) or cross-linked sepharose (grades 2B, 4B or 6B) (col. 3, lines 26-32), in order to provide removal of albumin from a fluid.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Grahnen et al. in view of Spring et al. further in view of Degen et al., an agarose support that is not cross-linked for binding albumin as taught by Travis et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent support technique and since the same expected binding function would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

### ***Response to Arguments***

6. Applicant's arguments with respect to the rejection of claims 1, 2, 4, 6 and 24-27 under 35 USC 103(a) over Sjöholm et al. in view of Spring et al. further in view of Degen et al. have been considered and are persuasive and the rejection has been withdrawn.

7. Applicant's arguments filed 15 January 2009 regarding the rejection of claims 1-6 and 24-27 over Grahnen et al. in view of Spring et al. further in view of Degen et al. have been fully considered but they are not persuasive. The rejections of claims 2-4

and 24-27 have been withdrawn in light of applicant's cancellation of these claims. Regarding claims 1, 5 and 6, applicant argues that Grahnen et al., Spring et al. and Degen et al. do not teach an apparatus for binding albumin. Applicant's argument is not persuasive because the claim is drawn to a product that is a device and such a limitation of binding to a certain analyte is drawn to intended use of the device and does not provide any additional structural limitations required for the device to perform the intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device of Grahnen et al. in view of Spring et al. further in view of Degen et al. teaches the structural elements required by the claim and is therefore capable of performing the recited intended use.

Regarding the rejection over Grahnen et al. in view of Spring et al. further in view of Degen et al., applicant further argues that Grahnen et al. specifically teaches that the sepharose must be cross-linked because Grahnen et al. state that when the bromosulphophthalein was treated without Sepharose CL insignificant changes were seen in the ultraviolet and visible absorption spectra. However, this passage does not teach away from using non cross-linked sepharose because the passage does not state that the treatment is performed with the non cross-linked Sepharose 4B only. The passage implies that the bromosulphophthalein was performed with no Sepharose at all to produce the less desirable results. Furthermore, if a column is formed with only the



non cross-linked sepharose, all disclosures of non-preferred embodiments must be considered. *In re Nehrenberg*, 126 PQ 383. *In re Boe*, 148 PQ 507. *In re Mill and Palmer*, 176 PQ 196 (CCPA 1972) . *In re Simon*, 174 PQ 114. *In re Lamberti et al.*, 192 PQ 278 (CCPA 1976). Since the column is formed with the non cross-linked sepharose, such a column reads on the rejected claims.

8. A new ground(s) of rejection is made in view of applicant's new claims 54 and 55 requiring an epoxy-activated support that is non cross-linked agarose. The new ground of rejection is made over Travis et al. teaching the functional equivalence between cross-linked and non cross-linked sepharose, which is an agarose.

#### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/  
Patent Examiner, Art Unit 1641